

# **Sufentanil Sublingual Microtablet System versus Intravenous Patient-Controlled Analgesia with Morphine for Postoperative Pain Control: A Randomized, Controlled Trial**

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## **Abstract**

**Background:** Problems with intravenous patient-controlled analgesia (IV PCA) are well-known, including invasive route of delivery and pump programming errors. The primary objective of this study was to evaluate patient satisfaction with a novel sublingual sufentanil PCA system (sufentanil sublingual microtablet system 15 mcg with a 20-minute lockout interval; SSMS) to IV PCA morphine 1 mg with a 6-minute lockout interval (IV PCA MS) for the management of acute post-operative pain.

**Methods:** This was a randomized, open-label, 48-hour non-inferiority study with optional extension to 72 hours at 26 US sites enrolling patients scheduled for elective major open abdominal or orthopedic (hip or knee replacement) surgery. The primary outcome measure was the proportion of patients who responded “good” or “excellent” (collectively “success”) at the 48-hour timepoint on the Patient Global Assessment of method of pain control (PGA48).

**Results:** A total of 357 patients received study drug and 78.5% vs. 65.6% of patients achieved PGA48 “success” for SSMS versus IV PCA MS, respectively, demonstrating non-inferiority ( $p < 0.001$  using the one-side Z-test against the non-inferiority margin) as well as statistical superiority for treatment effect ( $p=0.007$ ). Patients using SSMS reported more rapid onset of analgesia and patient and nurse ease of care and satisfaction scores were higher than IV PCA MS. Adverse events were similar between the two groups, however, SSMS had fewer patients experiencing oxygen desaturations below 95% compared to IV PCA MS ( $p=0.028$ ).

**Conclusions:** SSMS is a promising new analgesic technology that may address some of the concerns with IV PCA.